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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/469,530	12/22/1999	CHRISTIAN DAMPEIROU	GEI-075	5073
20311	7590	05/06/2004	EXAMINER	
MUSERLIAN AND LUCAS AND MERCANTI, LLP 475 PARK AVENUE SOUTH NEW YORK, NY 10016			WELLS, LAUREN Q	
		ART UNIT	PAPER NUMBER	
		1617		

DATE MAILED: 05/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/469,530	DAMPEIROU ET AL.
	Examiner Lauren Q Wells	Art Unit 1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 29 January 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 20-27,29-31,33 and 35 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 20-27,29-31,33 and 35 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____.
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____.

DETAILED ACTION

Claims 20-27, 29-31, 33 and 35-36 are pending. The Amendment filed 1/29/04, amended claims 22-27, 30-31, 33, and 35-36, and cancelled claim 28.

Applicant's amendment of 1/29/04 to claim 27 is sufficient to overcome the objection to this claim in the previous Office Action.

Applicant's amendment of 1/29/04 to claim 22 is sufficient to overcome the 35 USC 112, 1st paragraph, rejection over this claim in the previous Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The term "lycra" and the phrase "of about 10cm thickness" are new and not supported by the original disclosure.

Applicant argues, "With respect to "elastane", this has been replaced by the term "lycra" which, as can be seen from the definition of elastane submitted herewith is well known commercial fiber sold by DuPont". This argument is not persuasive, as the definition provided is in French. The Examiner is unable to translate French into English.

The rejection of claim 26 under 35 U.S.C. 112, 1st paragraph, is MAINTAINED for the reasons set forth in the Office Action mailed 10/23/03, and those found below.

Applicant states, “it is believed that they are clearly supported by pages 2 and 3 of the application as filed”. This argument is not persuasive, as pages 2 and 3 provide no support for “an adhesive member selected from the group consisting of acrylic copolymer and a copolymer of polyethylene glycol and polypropylene glycol”. The only thing that is similar to that recited in claim 26, the Examiner finds on page 3, which states an adhesive base with an acrylic polymer base and a veil of polypropylene placed on the outside of a siliconated protective item. This statement is not supportive of claim 26.

The rejection of claims 22 and 26 under 35 U.S.C. 112, 2nd paragraph, is MAINTAINED-in-part for the reasons set forth in the Office Action mailed 10/23/03, and those found below.

- i) While claim 26 has been amended to recite “adhesive agent”, there is still insufficient antecedent basis for this limitation in the claim, as claim 20 recites no such “adhesive agent”.
- ii) The rejection over claim 22, regarding the phrase “covered with a self-adhesive emulsion of the active ingredients containing latex”, the term “work”, and the phrase “allergic polyurethane”, is maintained for reasons of record, and Applicant provided no arguments toward these rejections.

Applicant’s amendment to claim 22 and argument over the term “stocking stitch casing” is sufficient to overcome the rejections of (i) 1., 2., 3., 4., 5., and 8, in reference to the phrase “stocking stitch casing”, in the previous Office Action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20-24, 26, 31, 33, 35, 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crotty et al. (5,985,300) in view of Binutu et al. (Planta Med.) in further view of Kelly et al. (6,146,668).

The instant invention is directed toward a composition containing 0.75-40% of a thickener, 3-85% of a composition containing active ingredients applied on an adhesive porous dressing, wherein the actives are selected from extracts of red clover, hop, common Ladies' mantle, sage, and liquorice, and an extract of Kigelia Africana or Kigelia pinnata.

Crotty et al. teach the delivery of skin benefit agents via adhesive strips. The product is a strip including a flexible substrate sheet onto which a composition containing an adhesive polymer is deposited. Herbal extracts are taught as skin agents. Licorice, red clover flow, sage, and soybean extracts are taught as particularly suitable. The extracts comprise from 0.00001-40% of the composition. Wetting agents such as propylene glycol, polyethylene glycol and mixtures of these with water is taught. Gel forms of the composition, wherein the compositions are thickened with thickening agents such as carbomer are taught. Acrylic copolymers are taught as suitable for making up the adhesive films. The substrates can be occlusive or non-occlusive and can be made of materials such as cotton and thermoplastic fibers. The substrates may be woven or nonwoven. Fragrances and colorants are taught as additives. The reference fails to

teach the percent weight of the thickener and Kigelia extracts, and fails to explicitly teach isoflavones in the soybean extract. See abstract; Col. 2, lines 19-35; Col. 3, line 13-Col. 4, line 26; Col. 5, line 29-Col. 6, line 53; Col. 8, lines 10-39.

Binutu et al. teach extracts of Kigelia pinnata as having antibacterial and antifungal activity. See abstract.

Kelly et al. teach soya (soy bean extracts) as comprising large quantities of isoflavones, wherein each extract of soya comprises from 0.05-0.3% isoflavone. See Col. 1, lines 46-64. Thus, the soybean extracts of Crotty comprise isoflavones. Since Crotty teaches the extracts as comprising 0.00001-40% of the composition, and since each soy extract comprises 0.05-0.3% isoflavone, the range of isoflavones recited in instant claim 36 is met.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add Kigelia pinnata extract, as taught by Binutu et al., to the composition of Crotty et al. because Crotty et al. teach that antimicrobial agents can be added to their compositions and because of the expectation of achieving a product that is natural, that protects the skin from microbes, and that extends the self-life of the product by providing protection against bacterial invasion.

While the amount of thickener is not explicitly taught, it would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the thickener as comprising 0.75-40% of the composition because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

The phrases “on a piece of ladies’ clothing” and “placed inside an adhesive porous dressing” in claims 20-22, are directed to the intended use of the instant product. Thus, this limitation is not given patentable weight. It is respectfully pointed out that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claims 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crotty et al. in view of Binutu et al. and further in view of Kelly et al. as applied to claims 20-24, 26, 31, 33, 35, 36 above, and further in view of Hyldgaard et al. (WO 98/05294).

Crotty et al., Binutu et al., and Kelly et al. are applied as discussed above. The references lack a binding agent.

Hyldgaard et al. teach cosmetic compositions. Hydrolyzed wheat gluten is taught as forming a protective layer on the skin surface. See abstract; page 11, lines 15-23.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add hydrolyzed wheat gluten, as taught by Hyldgaard et al., to the combined composition because of the expectation of achieving a product that protects the skin from external invasion and which increases the amount of active agent that is actually delivered directly to the skin.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crotty et al., Binutu et al., and Kelly et al. as applied to claims 20-24, 26, 31, 33, 35, 36 above, and further in view of Bara et al. (5,637,291).

Crotty et al., Binutu et al., and Kelly et al. are applied as discussed above. The reference lacks chitin.

Bara et al. teach cosmetic compositions. Chitin and carbomer are taught as interchangeable gelling agents, wherein gelling agents comprise from 0.1-10% of the composition. See Col. 3, line 59-Col. 4, line 5.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute chitin, as taught by Bara et al., for the carbomer taught by the combined references because of the expectation of achieving equivalent cosmetic thickening effects.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crotty et al., Binutu et al., and Kelly et al. as applied to claims 20-24, 26, 31, 33, 35, 36 above, and further in view of Nakamura et al. (5,676,957).

Crotty et al., Binutu et al., and Kelly et al. are applied as discussed above. The reference lacks butylene glycol.

Nakamura et al. teach propylene glycol, butylene glycol, and polyethylene glycol as interchangeable wetting agents. See Col. 4, lines 36-44.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute butylene glycol for the propylene glycol or polyethylene glycol of the combined references because of the expectation of achieving equivalent skin wetting effects.

Response to Arguments

Applicant argues, “Applicant’s respectfully traverse these grounds of rejection since one skilled in the art would not combine the references as the Examiner has done with the benefit of Applicants’ disclosure”. This argument is not persuasive. In response to applicant’s argument that the examiner’s conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant’s disclosure, such a reconstruction is proper.

See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant argues, “Applicants’ invention is not a composition containing at least one active plant extract for any therapeutic purpose but, rather is a cosmetic composition containing as active ingredients a combination of several compounds including at least one plant extract having an estrogenic activity and an extract of the plant Kigelia Africana or Kigelia pinnata which has a positive action on the development of the bust and a positive action on the firmness of tissue and this is in no way taught by the references cited by the Examiner”. This argument is not persuasive. First, this argument is not even commensurate in scope with the instant claims which do not recite any positive actions on the bust or tissue, or estrogenic activity. Second, this argument is not commensurate in scope with the instant claims because the instant claims are directed toward a composition and not toward methods of treatment or any other types of methods. Third, it is respectfully pointed out that Applicant is arguing intended use. It is respectfully pointed out that a recitation of the intended use of the claimed invention must result

in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Furthermore, Applicant argues that their composition is explicitly a cosmetic. The Examiner respectfully points out that the recitation “cosmetic” has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Additionally, it is pointed out that all of the instant references are directed toward cosmetic compositions. Furthermore, the Examiner respectfully points out that Applicant has mischaracterized their invention. The instant invention is not a cosmetic composition containing as active ingredients a combination of several compounds including at least one plant extract having an estrogenic active and an extract of the plant *Kigelia Africana* or *Kigelia pinnata*. The instant claims are directed toward a composition comprising 1) a thickening agent; 2) an extract selected from red clover, Hop, common Ladies’ mantle, Sage, or Liquorice; and 3) an extract of *Kigelia Africana* or *Kigelia pinnata*.

Applicant argues, regarding Crotty et al, “the reference fails to teach the presence of Kigelia extracts and the explicit presence of isoflavones in the composition even if the latter is inherently present nor is there any suggestion of Applicants’ cosmetic compositions”. This argument is not persuasive. In response to applicant's arguments against the references individually, it is respectfully pointed out that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

It is respectfully pointed out, as set forth in the instant rejection, that it is the combination of references that teaches all the limitations of the instant claims. For reasons of record, there is motivation to combine the references to arrive at the instant invention.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is 571-272-0634. The examiner can normally be reached on M&R (5:30-4).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

lqw



SREENI PADMANABHAN
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